

# EXHIBIT 19

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Report of Matthew Perri III in Case no. 17-OP-45004 (N.D. Ohio) and Case No. 18-OP-45090 (N.D. Ohio)

Confidential and Subject to Protective Order

Expert Report of Matthew Perri III, BS Pharm, PhD, RPh

March 25, 2019

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122. Defendants' aggressive<sup>244</sup> marketing put patient welfare at risk through increased prescribing of opioids. The Defendants' marketing strategy for opioids was designed to turn drug features into drug benefits, create desirable positioning in Customers' minds, and stimulate prescriptions for opioids. Each of these activities is consistent with marketing principles, but not with industry standards for the marketing of dangerous drugs like opioids.

**Marketing Information Bias Toward Benefits, not Harms**

123. It should be noted that Defendants' marketing documents sometimes reference the need to disclose safety information for drugs, consistent with FDA-approved indications and prescribing information contained in the PI.<sup>245</sup> In one Kadian plan, PSRs were specifically directed to discuss safety considerations with prescribers during sales calls.<sup>246</sup> However, the preponderance of

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propah dose. Exalgood. Exalgood. It's Exalgood.); MNK-T1\_0006835316 (audio, When Less is More); MNK-T1\_0007033463 (The interesting physician parody, stay focused my friends); TEVA\_MDL\_A\_00717855 (Actiq sales training); TEVA\_MDL\_A\_00715630 (News clips); TEVA\_MDL\_A\_00717114 ("Doug" a construction worker); TEVA\_MDL\_A\_00717111 (Converting Actiq prescribers); TEVA\_MDL\_A\_00717116 (Actiq v Fentora); TEVA\_MDL\_A\_00717117 (Pain Lingers); TEVA\_MDL\_A\_00717110 (Patient and Doctor, BTP).

<sup>244</sup> Reference is also made to aggressive marketing by Defendants and others, see e.g., Riddle\_Purdue Deposition pp.33-34, 134; Wickline\_MNK Deposition p.147; OxyContin Launch Plan, 1995, PURCHI-003286149; 2013 Preliminary Business Plan, July 31, 2012, JAN00019880; Cohen, June 28, 2011 email with subject: Oxymorphone ER 7.5mg & 15 mg, ALLERGAN\_NDL\_00132475; Covidien Pharmaceuticals Internal Newsletter Article, April 26, 2010, Pennsaid and Exalgo, MNK-T1\_0000857461; Burlakoff October 2, 2013 email, INSYS-MDL-000392811; ENDO-OPIOID\_MDL-00439663; Mallinckrodt-Wickline-008, Meyer May 30, 2013 email with the subject FW: Operation Change Agent; MKN\_TNSTA00311798, "Meanwhile, pill manufacturers launched aggressive marketing campaigns promoting the drugs." "At around the same time, the companied that manufactured these narcotics – including Purdue Pharma, Johnson & Johnson, and Endo Pharmaceuticals – began to aggressively market their products for long-term, non-cancer pain, including neck and back pain" In Mallinckrodt-Wickline-023; Van Zee, A. The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy. Am Journal of Public Health, 2009; 99(2): 221-227; Key Strategic Imperative: Customer-Facing Organizational Readiness, p.2, MNKT-T1\_0000184758; Exhibit Endo-Chapman-6, Statement of Unites States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and its Executives for Illegally Misbranding Oxycontin; Note: Mr. Gasdia at Purdue did not personally agree with this characterization of Purdue's marketing, yet, described efforts that fit a marketing definition of aggressive marketing (Gasdia\_Purdue pp.126-136).

<sup>245</sup> While cautionary statements were noted in the PIs of all Defendants, as noted above, the PI is not generally relied on in personal selling situations. See also e.g., Cycle 1 Meeting, Training Workshops, JAN00085130, for a slide entitled: "Compliance is Essential."

<sup>246</sup> See also, e.g., Kadian 2011 National Sales Meeting, "Putting it all together," 132\_ACTAVIS0413281, Do's and Don'ts.

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Defendants' messages (discussed in detail below) focused on translating drug features into drug benefits, and downplayed information that would serve to discourage prescribing, including potential harms.

124. Like the Kadian plan, in a 60-slide sales training presentation for Nucynta, Janssen notes at the outset that PSRs should always "disclose safety information for all company-promoted products." This is the only mention of safety in this presentation; yet, there is ample content instructing PSRs on how to communicate drug benefits, including copay cards and other selling messages. The "core" messages in this presentation include: "Powerful Efficacy, Favorable Tolerability & Discontinuation Rates, Mechanism of Action, Dosing and Titration, Access and Affordability."<sup>247</sup> Other Janssen programs provided similar training themes with a focus on benefits and selling, not on reasons to be cautious or to choose a non-opioid alternative.<sup>248</sup>
125. In a different kind of example, David Horton, a Product Manager from Mallinckrodt, was asked to identify key talking points for an upcoming meeting where face-to-face promotion of Xartemis, an extended-release oxycodone/acetaminophen, would occur. If the company's focus was to always provide a balance of information on the benefits and harms, it is certainly not reflected in this communication. Mr. Horton's list of talking points included: "*set up the unmet need; establish a specific patient appropriate for XARTEMIS XR; Sell the benefits of IR AND ER – fast acting/long lasting; promote the impact of simple, twice daily dosing; and, close to action with specific patients.*" In the narrative and instruction provided in this instance, no mention of any cautionary information is made.<sup>249</sup> In another Mallinckrodt sales leadership training for Xartemis, which included multiple training objectives, there is no training related to the dangers

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<sup>247</sup> Retail Training Workshop, JAN00089339.

<sup>248</sup> See e.g., Retail Training Workshops, JAN00079899. There were other similar presentations related to Institutional sales, such as JAN00081397.

<sup>249</sup> 20\_MNK-T1\_0000130448, 2/19/2015 email with subject, RE: ECRM.

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of opioids (harms), only training on how to achieve sales objectives such as “more rapid and sustainable sales.”<sup>250</sup>

126. The FDA warning letters cited above also support the proposition that Defendants minimized risk information in their marketing. These letters describe the FDA’s position on certain marketing for MS Contin, Duragesic, Avinza, Fentora, Ultram, Embeda, Kadian, and Nucynta.
127. Defendants also expressed views related to the communication of risk information about their drugs. For example, Mr. Bingol, a former Senior Director of Marketing at Endo who had responsibility for Opana and Opana ER, was asked about the issue of the history of abuse of oxymorphone. According to his testimony, Endo promoted the drug in accordance with its label, but never provided education to its sales force, health care providers or patients about history of abuse of oxymorphone pills.<sup>251</sup> Mr. Romaine, a former Vice President of Sales at Endo confirmed PSRs spent most of the time during their sales calls discussing the “features and benefits” of the products and did not, for example, review the black box warnings verbatim during their sales calls.<sup>252</sup>
128. Mr. Boyer, former President and CEO of Teva, testified that using sales representatives to communicate with doctors about the proper use and risks of opioids was cost prohibitive and not done by Teva. He further indicated that other, less costly ways of communicating this information were also not used by Teva.<sup>253</sup> Mr. Webb, testifying for Mallinckrodt, was asked about risk information related to addiction in marketing materials. He stated, “—refresh my memory on what we consider the fair balance in the important patient risk information that we put on our material. But I know that we share with the physician, anytime opioids were being

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<sup>250</sup> 23\_MNK-T1\_0000132919, Field Sales Tactical Brand Planning.

<sup>251</sup> Bingol\_Endo Deposition pp.334-340 and Exhibit 36.

<sup>252</sup> Romaine, Larry\_Endo Deposition pp. 501-503.

<sup>253</sup> Boyer\_Teva Deposition pp.317-320.

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189. Using these general themes, Defendants used a battery of specific marketing messages designed to increase product awareness and systematically remove existing barriers: effectively changing how Customers viewed opioids. Other experts evaluated the nature of these messages and provided the opinions that Defendants' marketing messages were false, misleading, inaccurate, or designed to misstate the risks and benefits of Defendants' drugs. Defendants also downplayed the negative aspects of their products and convinced prescribers, and others, to use opioids sooner in treating pain, at higher doses, and for a broader spectrum of pain types.
190. Further, Defendants' marketing activities with influencers, KOLs, and professional/advocacy organizations gave their messages more credibility because Defendants hid their funding and influence from the medical community and the public. This created the perception that the information from these marketing efforts was unbiased and more scientific which mislead Customers about the impartiality of the messages.
191. The marketing strategies and tactics Defendants used were effective at gaining market share and expanding the overall market for opioids. This led to a dramatic rise in utilization of opioids in the U.S.
192. Defendants violated marketing standards by creating and disseminating false or misleading marketing messages that downplayed or minimized the risks associated with opioids, while emphasizing the benefits of their drugs, and by disguising their support of activities aimed at increasing sales of their own products.

**V. SIGNATURE**

193. I reserve the right to amend my opinions in this matter considering any new or additional information.



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Matthew Perri III BS Pharm, PhD, RPh

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Date